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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/672,049	09/29/2000	Johannes Platzek	SCH-1722	2997

23599 7590 11/19/2003

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EXAMINER

WELLS, LAUREN Q

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 11/19/2003

23

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/672,049

Applicant(s)

PLATZEK ET AL.

Examiner

Lauren Q Wells

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) 6-15, 17-22, 26-38 and 41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 16, 23-25, 39 and 40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 17. 6) ☐ Other: _____

DETAILED ACTION

Claims 1-41 are pending. Claims 6-15, 17-22, 26-38 and 41 are withdrawn from consideration, as they are directed to non-elected subject matter. The Amendment filed 9/9/03, Paper No. 19, amended claims 1 and 39, and added claim 41.

Applicant's amendment to claim 39 is sufficient to overcome the 35 USC 112 rejection in the previous Office Action.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Germany on 9/29/99. It is noted, however, that applicant has not filed a certified copy of the German application as required by 35 U.S.C. 119(b).

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/7/03 has been entered.

Election/Restrictions

Newly submitted claim 41 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

1) Methods of use were restricted into a different group from galenical formulations in the Restriction Requirement mailed 11/19/01, Paper No. 6.

2) The instantly examined claims and claim 41 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case MRI imaging can be practiced with a number of materially different products, such as Gd-DOTA, Gd-DTPA, Gd-labeled albumin, Gd-labeled albumin, chromium labeled red blood cells, and many other compounds/complexes.

Accordingly, claim 41 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 16, 23-25 and 39-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Platzek et al. (WO 97/26017) in view of Milius et al. (New J. Chem 1992) or in view of Riess et al. (EP 548096).

The instant invention is directed toward a galenical formulation comprising paramagnetic perfluoroalkyl and diamagnetic perfluoroalkyl compounds.

Platzek et al. teach perfluoroalkyl-substituted, paramagnetic metal complexes for use in NMR, X-ray diagnostics, radiodiagnostics, and radiotherapeutic agents. Specifically disclosed is Complex I, Rf-L-M, wherein Rf is C₈F₁₇, L is a direct bond, and M is that of general formula

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XI of the instant invention when $Z1=Gd$, $q=1$, $p=0$. The reference lacks diamagnetic perfluoroalkyl-containing substances. See pg. 2-pg. 3; pg. 162-180.

Milius et al. teach perfluoroalkylated anionic sugar phosphodiesteres that are utilized in numerous biomedical applications, such as in vivo oxygen carriers, contrast agents, and drug delivery systems, as surfactants or co-surfactants. Disclosed are compounds of formula $Rf-L1-B2$, wherein Rf is C_8F_{17} , $L1$ is CH_2CH_2 , and $B2$ is a disaccharide. The use of these compounds in fluorocarbon emulsions impart improved control over the characteristics of injectable fluorocarbon emulsions, including particle sizes and size distributions, viscosity, long term storage stability, intravascular persistence, aggregability, rate of and response to phagocytosis, and biodistribution. See entire disclosure.

Reiss et al. teach compounds of formula (XVI)— $Rf-L1-B2$ - of the instant invention, wherein Rf is a fluorinated radical of 2-18 carbon atoms, $L1$ is a straight chain carbon chain with up to 20 carbon atoms that contains $-S-$, and wherein $B2$ is a polyhydroxyalkyl chain with at least two hydroxyl groups, see pg. 3, lines 10-56, which depict formula (I). These compounds can be used in preparations intended to facilitate diagnosis, in particular by radiography, sonography or NMR, and thus can be used as contrast agents or markers, see pg. 9, lines 4-10 and lines 35-36.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the perfluoroalkyl-substituted, paramagnetic metal complexes of Platzek et al. and the perfluoroalkyl anionic sugars of Milius et al. because of the expectation of achieving an intravenous fluorocarbon emulsion for imaging, with optimum particle sizes and size

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distributions, viscosity, long term storage stability, intravascular persistence, aggregability, rate of and response to phagocytosis, and biodistribution.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the perfluoroalkyl-substituted, paramagnetic metal complexes of Platzek et al. and the compounds of Reiss et al. because of the expectation of achieving enhanced contrast images and because it is obvious to combine two compositions taught by the prior art to be useful for the same purpose to form a third composition that is to be used for the very same purpose. In re Kerkoven, 205 USPQ 1069 (CCPA 1980).

Regarding the ratios and percent weights, it is respectfully pointed out that it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Response to Arguments

Applicant argues, "Rather, Milius relates to a certain new perfluoroalkyl containing compound which is particularly effective as an emulsifier of various fluorocarbon compositions. . . There is no reason for a skilled worker to combine Milius with Platzek et al. to provide a new galenical formulation useful as a contrast medium, or for any other purpose". This argument is not persuasive. First, this argument is not commensurate in scope with the instant claims, as the instant claims do not recite a contrast medium. Second, for the reasons stated in the above rejection there is motivation to combine the two references. The surfactants of Milius are specifically taught for use with contrast agents for diagnostics, wherein the contrast agents are fluorocarbons.

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Applicant's arguments toward Mattrey are moot, as the Examiner has in no way relied upon Mattrey.,

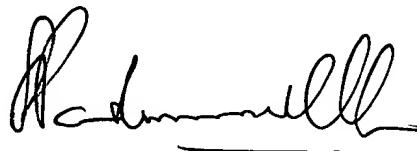
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on M-F (7-4:30), with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (703)305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw


SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER

11/17/03